

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-503V

November 28, 2006

LESLIE J. KLAUSS,

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Petitioner,

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v.

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Hepatitis B vaccine; seven-week interval to GBS; how prove causation?

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SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

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Respondent.

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ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated July 26, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10, et seq., alleging that she had an unspecified reaction to hepatitis B vaccine. Medical records that she filed on March 29, 2002 state that she had a variant of

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Guillain-Barré Syndrome (GBS) as a consequence of receiving hepatitis B vaccine. The medical records show an interval of seven weeks, a considerable period of time, between petitioner's third hepatitis B vaccination (April 18, 1996) and the onset of her neuropathy (June 5 or 6, 1996).² The undersigned views it highly unlikely that petitioner will find a medical expert to support her allegations. Petitioner is ORDERED TO SHOW CAUSE by **January 26, 2007** why this case should not be dismissed.

A prior Order to Show Cause was issued in this case on April 4, 2002. Petitioner's response on May 30, 2002 was that it was premature for petitioner to seek a medical expert because petitioner wanted to go through the Omnibus proceeding on hepatitis B vaccine-demyelinating diseases. That proceeding is now finished.

FACTS

Petitioner was born on March 28, 1964. Med. recs. at Ex. 1, p. 1. She received her second hepatitis B vaccination on October 13, 1995. Id. The records submitted do not indicate when she received her first hepatitis B vaccination although she alleges in her petition that she received her first hepatitis B vaccination in October 1995 and her second hepatitis B vaccination in November 1995. There is no record of a hepatitis B vaccination in November 1995.

The records dated September 28, 1995 show that she had a history of a bulging disk in her spine and a tender L4-5 area. Id. The history also shows that she had a closed head injury which she described as a cerebral concussion followed by post-traumatic headaches. Med. recs.

² Moreover, petitioner had diarrhea when she sought medical help for her neuropathy. *Campylobacter* has been causally linked to GBS

at Ex. 1, p. 49. Petitioner is a respiratory therapist who was occupationally trained in nursing. Med. recs. at Ex. 1, p. 30.

On December 28, 1995, two and one-half months after she received her second hepatitis B vaccination, petitioner went to her doctor complaining of fatigue with dizziness off and on for the prior week with ringing in her ears. Med. recs. at Ex. 1, p. 1.

On February 17, 1996, four months after she received her second hepatitis B vaccination, petitioner went to her doctor complaining of a chronic headache and episodes of blurred vision. Id. She later informed a doctor that she had bilateral axillary lymphadenopathy. Med. recs. at Ex. 1, p. 30.

On April 18, 1996, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 1, p. 1.

On June 19, 1996, petitioner saw Dr. William Dam, complaining that starting on June 6, 1996, seven weeks after she received her third hepatitis B vaccination, she had left arm numbness and visual changes, including flashing of light, and developed a severe migraine headache. The next morning, she awoke with bilateral upper and lower extremity numbness which lasted for five days and went away. She informed Dr. Dam that in February 1996, she had bilateral axillary lymphadenopathy. Id.

She also saw Dr. Mahesh N. Parikh on June 19, 1996, and told him that she had a history of difficulty passing urine. She complained of migraine headaches off and on over the prior two months, but in the last ten days, extreme pain. She denied any blurriness. Med. recs. at Ex. 1, p. 33.

On June 21, 1996, petitioner saw Dr. Mohammad Zahid and told him her onset was on June 5, 1996 with symptoms of tingling and numbness in the upper extremities which progressively worsened until she could not walk or eat. Her right side was more significantly affected than her left. She also had diarrhea. She ate a lot but did not gain weight. For the prior two weeks, she noticed she was stronger in the morning but then progressively got weaker. She had mild hyperglycemia with a blood sugar of 167, and a family history of diabetes. Med. recs. at Ex. 1, pp. 28-29.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had variant GBS, but also that the vaccine was a substantial factor in bringing about her variant GBS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS, and did so in that case. Onset was 21 days (three weeks) after vaccination. 2006 WL 1006612, at *2.

Respondent's expert, Dr. Roland Martin, testified in the Omnibus hepatitis B vaccine-demyelinating diseases proceeding that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

In the instant action, the onset interval is seven weeks, too long according to the evidence in the Omnibus proceeding for there to be causation in fact. The undersigned doubts that petitioner will find expert medical support for her allegation. Petitioner is ORDERED TO SHOW CAUSE by **January 26, 2007** why this case shall not be dismissed.

IT IS SO ORDERED.

November 28, 2006
DATE

s/Laura D. Millman
Laura D. Millman
Special Master